November 4, 1999

VETERINARY SERVICES MEMORANDUM NO. 800.58

Subject: Sublicensing of Veterinary Biological Products

To: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics

I. PURPOSE

This memorandum establishes guidance for the sublicensing of a veterinary biological product from one licensed veterinary biologics establishment to another biologics establishment.

II. CANCELLATION

This memorandum cancels Veterinary Services Memorandum No. 800.58, dated December 24, 1984.

III. BACKGROUND

Sublicensing occurs when a licensed establishment transfers the technology to produce a currently licensed product to another (receiving) establishment. The receiving establishment, in order to produce and market this product, must obtain an establishment license (if it doesn't already have one) and a product license according to 9 CFR Part 102. This memorandum describes the requirements for sublicensing. (Note that in the text below, "licensed firm" or "original licensee" refers to the establishment transferring the product technology and applicant refers to the establishment receiving the product technology.)

IV. PROCEDURES

A. Licensing Requirements (General)

The firm (applicant) seeking to produce and market a product through sublicensing must submit the following items to the Center for Veterinary Biologics-Licensing and Policy Development (CVB-LPD):

1. *Application for an Establishment License* - An application for United States Veterinary Biologics Establishment License (APHIS Form 2001) and

supporting materials according to 9 CFR 102.3, when applicable. (Note: This does not apply if the firm already has an establishment license.)

2. *Application for Product License* - An application for United States Veterinary Biological Product License (APHIS Form 2003).

3. *Permission to Use Previously Filed Data* - Documented permission from the licensed firm transferring the technology for the applicant to support the current application using all appropriate research, field trial, and production data submitted to CVB-LPD when the product was previously licensed.

4. *Request to Transfer Materials* - A request to CVB-LPD for approval to bring necessary production materials into the applicant's production facility.

5. *Evidence of Technology Transfer* - Documented evidence from the licensed firm that the applicant has been provided all the necessary technical information and assistance that is needed to produce the product in the same manner as it was produced by the licensed firm.

6. *New or Amended Facilities Documents* - New or amended plot plan, blueprints, and legends of the applicant's production facilities, as applicable, in accordance with 9 CFR 108.

7. *Outline of Production* - An Outline of Production prepared in accordance with 9 CFR 114.8 and 114.9. All essential procedures must be identical with those of the licensed firm.

8. *Supporting Data* - Reports of the results of the applicant's tests as follows:

a. Tests for purity, identity, and virulence of seeds using methods stated in the Outline of Production.

b. An immunogenicity test conducted with product at or below the minimum level of potency used in the immunogenicity test when previously licensed. Conduct this test using the number of animals indicated for the 3-year repeat immunogenicity test in the Standard Requirement or using a number of test animals acceptable to CVB-LPD. For rabies vaccines,

however, conduct the immunogenicity test with the same number of animals as required in 9 CFR 113.209(b) and 113.312(b).

9. *Test Reports* - Veterinary Biologics Production and Test Reports (APHIS Forms 2008), prepared according to Veterinary Services Memorandum No. 800.53, for three consecutive satisfactory serials of the product.

10. *Labels* - Labels prepared according to 9 CFR 112. Support any changes in directions for use, warnings, or cautions from labels in use by the original licensee with additional valid data.

B. Licensing Requirements (Firms Under the Same Ownership)

When the firms transferring and receiving the product technology are owned by the same person (individual, partnership, or corporation), the receiving firm, must provide all the items listed in section A. above, except that retesting purity, identity, and virulence of seeds, conducting repeat immunogenicity tests on the product, and submission of such data as indicated in section A. 8. are optional.

C. Prelicense Testing

Before issuing a license, CVB will conduct confirmatory tests of seeds, cells, and production serials as appropriate.

/s/ Thomas E. Walton for

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